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## (54) Retrievable pessary.

(57) A retrievable pessary for intravaginal or intrarectal use comprises a solid body (6) comprising a pharmaceutically active ingredient; a net pouch (2) which encloses the body; and a withdrawal cord (8,10) attached to the pouch to enable the pessary to be withdrawn after use.

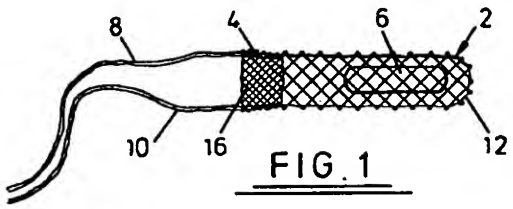


FIG. 1

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The present invention relates to a retrievable pessary for intravaginal or intrarectal use, which may be inserted and retrieved again once the pharmacologically active ingredient contained therein has been substantially released.

Controlled release pessaries are already known and typically comprise a solid polymer body containing a pharmacologically active substance, which is released in a controlled release or sustained release manner so as to provide a controlled dosage of the active substance over a prolonged time period. One such pessary sold for intravaginal use under the trade mark PROPESS contained a prostaglandin. Prostaglandins play an important role in the gravid uterus, at or near term in pregnancy. They induce structural changes in cervical smooth muscle fibres, resulting in softening and changes in shape that produce a ripening of the cervix. A sustained release of the prostaglandin is required over a time period of several hours just prior to birth. However, whilst these pessaries can be inserted relatively simply by the obstetrician, their removal may pose problems since it may be difficult to find and grip the pessary again.

Intravaginal articles, such as tampons, which have strings to allow removal of the device are already known. Tampon constructions are known from patent specifications GB 606527, GB 620586, GB 2025231, GB 2200285 and US 3815601. Generally speaking, these comprise absorbent bodies designed to absorb body fluids and are provided with a string for retrieval purposes. They do not include active agents. The strings are usually attached directly to the device itself. Unfortunately, this is not necessarily appropriate for controlled release devices with which the present invention is concerned, since the solid polymer body containing the pharmacologically active ingredient often lacks the necessary physical strength or integrity to provide a satisfactory anchoring point for the removal string.

Intrauterine contraceptive devices are also known and are disclosed, for example in patent specification WO 82/02489. These may comprise an active ingredient such as a spermicide (which is non-systemic), but it is practically speaking not possible to include any retrieval cord since this would obstruct sexual intercourse.

It is an object of the present invention to mitigate the problems mentioned above, and to provide a pessary which is more easily and reliably retrievable.

Generally speaking, the present invention involves using a net having sufficient strength to attach retrieval means thereto.

In particular, the present invention provides a retrievable pessary for intravaginal or intrarectal use which comprises;

- a solid body comprising a pharmacologically active ingredient adapted to be released in a controlled manner from the body;
- net retaining means formed of a biologically acceptable material and engaging the solid body; and
- elongate retrieval means attached at one end thereof to the net retaining means to enable the pessary to be withdrawn from the vagina or rectal cavity after use.

The nature of the solid body is not of primary importance but the invention is particularly applicable to bodies having insufficient strength to retain normal retrieval means. The solid body is usually a polymer but might be any other type of controlled release structure such as a leachable-glass.

Generally the solid polymer body is non-biodegradable (in contrast to certain biodegradable or erodable controlled release systems known in the art) such that the solid body is not dispersed inside the patient but requires to be removed after release of the pharmacologically active ingredient to the extent desired. Many such non-biodegradable solid polymer bodies are known in the art and typically comprise water-swellable polymers capable of absorbing substantial amounts of aqueous liquid to increase their size several fold. For example, controlled release polymers based on cross-linked polyethylene glycol are capable of swelling to 1.2 to 5, particularly 1.5 to 3 times (on a weight basis) the original unswollen state. Such swellable hydrogels are typically described in patent specifications GB 2047093 and GB 2047094.

The period of time over which the controlled release of pharmacologically active ingredient is to take place will vary according to the nature of the ingredient and the pharmacologically effect to be achieved. In the case of prostaglandins, release is usually required over a relatively short time period, for example 1 to 10 hours. However, the retrievable pessary of the present invention has more general utility for the administration of drugs into the body which may be absorbed through the vaginal or rectal wall into the patient's system. In such cases, controlled release may be arranged to occur over days, weeks or even months according to the nature of the active ingredient and the desired pharmacological effect. Release of the active ingredient may be controlled by diffusion through the solid polymer body to its outer surface, or may be controlled by solubility of the active ingredient in the surrounding body fluid, depending on the nature of the active ingredient itself. The rate of release usually depends on a variety of factors, such as the shape, thickness and degree of cross-linking of the solid polymer body, the nature of the active ingredient and the nature of the polymer itself.

The administered dose may be controlled by removing the pessary prior to exhaustion of the active ingredient, for example when the appropriate pharmacological response has been delivered.

The net retaining means engage the solid body so as to provide a firm anchorage for the elongate retrieval means, despite any lack of inherent strength in the solid body itself. The net retaining means may be embedded within the solid body, but is more preferably in the form of a pouch which encloses the solid body.

The net retaining means is formed of a biologically-acceptable perforate material, such as a net (including knitted, woven and non-woven materials, synthetic nets and expanded porous films).

Where the polymer swells in use, a pouch should be arranged such that whilst conforming to the initial size of the polymer body, is capable of stretching as the polymer swells. Knitted structures are particularly useful for this. Alternatively, the material from which the pouch is made may itself have the desired stretchability or elasticity.

It is particularly preferred that the pouch be produced in a seamless manner e.g. by circular knitting, so as to minimise seams or other protrusions which might lead to irritation within the patient. The pouch will usually have a slit, slot or other aperture for insertion of the solid polymer body.

Usually, the total length of the retrievable pessary is 25-35cm. The pouch is generally of length 1 to 15 cm (preferably 5 to 15 cm for a suppository and 4 to 10 cm for a vaginal pessary) and of width 0.3 to 1 cm.

In one embodiment of the invention, the elongate retrieval means are integrally formed with the pouch, for example by knitting a continuous tape including a pouch portion into which the polymer body is inserted. Alternatively, a continuous knitted tube could be employed which is sealed at one end (using ultrasonics or heat) before inserting the solid body and sealing across the tube to create a pouch around the body, and to leave a long free end (which may in turn be sealed) as retrieval means.

In a second embodiment, the elongate retrieval means is separate from the pouch (and is typically in the form of a cord of the type used for withdrawal of tampons) which is integrated into the structure of the pouch during formation thereof. Preferably, the retrieval cord has two long ends and a central section passing down either side of the pouch from its open end and around its closed end. A neck piece may also be provided around the open end of the pouch. This prevents ripping and fraying of the net, and helps prevent accidental removal of the pessary.

The elongate retrieval means are formed of a biologically-acceptable material, typically a synthetic or natural polymer such as a polyester optionally including cotton.

Embodiments of the present invention will now be described by way of example only with reference to the drawings which are to some extent schematic, wherein:

Figure 1 is a side view of a first embodiment in its initial state;

Figure 2 is a view of the pessary in a swollen state;

Figure 3 is a view of a second embodiment having an integrally formed retrieval tape; and

Figure 4 shows a second embodiment in its swollen state.

The embodiments shown in Figures 1 and 2 comprises a pouch 2 having a neck 4 and enclosing a controlled release swellable polymer body 6, a withdrawal cord having end portions 8, 10 and a central portion 12 is provided for retrieving the pessary.

The lozenge shaped polymer body 6 has a dry (and wet) length substantially 30mm (48mm), width substantially 9mm (15mm) and thickness 0.8 to 1.1mm (1.9mm) and is formed of a cross-linked polyethylene glycol. On swelling in contact with body fluids, it is capable of expansion of approximately 325% (i.e. takes up 325% by weight of water). The polymer allows for diffusion control release of a pharmacologically active ingredient (for example prostaglandin $PGE_2$) though many other applicable active ingredients will be known to the skilled man and the present invention is not limited to any particular one of these.

The pouch 2 is netted and formed of a texturised Dacron or Diolen polyester yarn of a single feed knitted construction formed on a Lilliput knitting machine. The seamless pouch is produced by circular knitting. The knitted construction imparts extensive elasticity to the pouch, which closely conforms to the shape of the polymer body 6 both in the initial and swollen states. The pouch is closed at one end and has an open end 16 through which the polymer body is introduced during assembly. The mouth area is strengthened by means of a neck piece 4 knitted from the same polyester yarn in a denser construction.

The retrieval cord comprises long end portions 8, 10 and a central portion 12 which extends down opposed sides of the pouch and around its closed end. The cord is sewn into the pouch during formation thereof so as to avoid the use of seams or adhesives.

The cord is sewn into the pouch by making the cord one of the two threads fed to a sewing machine. The cord is sewn down one side and around the end of a tube of the netted material (thereby

closing the end), and back up the other side. The pouch is trimmed to shape, before being turned inside out so that the cord runs around the inside of the pouch.

Once the polymer body 6 has been introduced into the net pouch 2, the open end 16 may be closed by means of a knot 14 in the retrieval cord. The free ends of the cord may also be knotted (not shown) or one of the strings can be cut short, so as to effectively leave a single retrieval cord.

The pessary is introduced in its non-swollen state into the patient leaving the retrieval cord hanging out. When retrieval is required, this is simply a matter of gentle pulling on the free ends of the retrieval cord so as to withdraw the swollen pessary.

Figures 3 and 4 show a second embodiment wherein the retrieval means is an integrally formed elongate tape 20. The tape is integrally formed on a double bed Rachelle frame from a texturised Dacron polyester yarn and comprises a pouch portion 22 and a closed end portion 24. A longitudinally extending slot 26 is provided for introducing the polymer body 6. Alternatively, the slot could extend transversely or at an angle to the longitudinal direction. Preferably the slot is adjacent to the closed end 24 of the pouch, but could in principal be anywhere on the pouch provided that the polymer body is effectively retained. The slot is located such that the end of the polymer body cannot inadvertently find its way into the slot, leading to loss of the body from the pouch. The tape, pouch, closed end and slot may be integrally formed on the knitting machine by appropriate programming thereof. The pouch portion 22 is arranged to be stretchable so as to substantially conform to the shape of the polymer body in both its initial and swollen states.

Insertion into a patient is carried out as before by a medical practitioner, and the device may be retrieved after use by means of the withdrawal tape.

Equally, the above-described embodiments could be adapted to take a suppository by minor adjustment of dimensions. A typical suppository is cylindrical with a rounded end and has dry (and wet) dimensions length 40mm (60mm), diameter 10mm (16mm); and a swelling of approximately 220%.

## Claims

1. A retrievable pessary for intravaginal or intrarectal use which comprises
   - a solid body (6) comprising a pharmacologically active ingredient adapted to be released in a controlled manner from the body;
   - net retaining means (22) formed of a biologically acceptable material and engaging the solid body; and
   - elongate retrieval means (20) attached at one end thereof to the net retaining means to enable the pessary to be withdrawn from the vagina or rectal cavity after use.

2. A pessary according to claim 1, wherein the solid body is non-biodegradable and non-erodable such that the body is not dispersed inside the patient in use.

3. A pessary according to any preceding claim, wherein the solid body is a water-swellable hydrogel.

4. A pessary according to any preceding claim, wherein the pharmacologically active ingredient is capable of being systemically absorbed into the patient.

5. A pessary according to any preceding claim, wherein the net retaining means comprises a pouch (22) enclosing the solid body.

6. A pessary according to claim 6, wherein the pouch is sized to accommodate any swelling of the solid body in use.

7. A pessary according to claim 5 or 6, wherein the net retaining means is a hollow tape provided with a slot (26) to insert the solid body, and an elongate extension (20) forming said retrieval means.

8. A pessary according to claim 7, wherein the hollow tape is integrally formed by knitting.

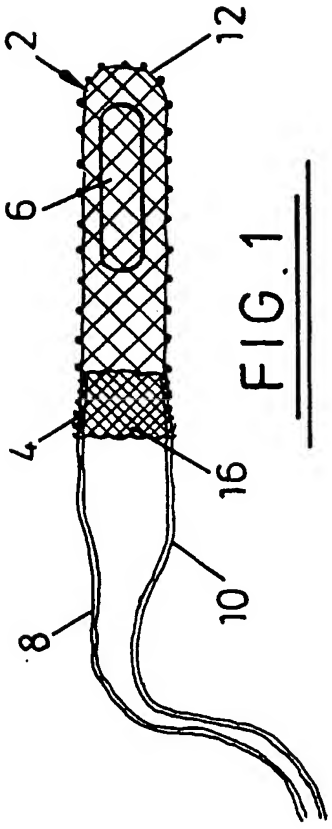


FIG. 1

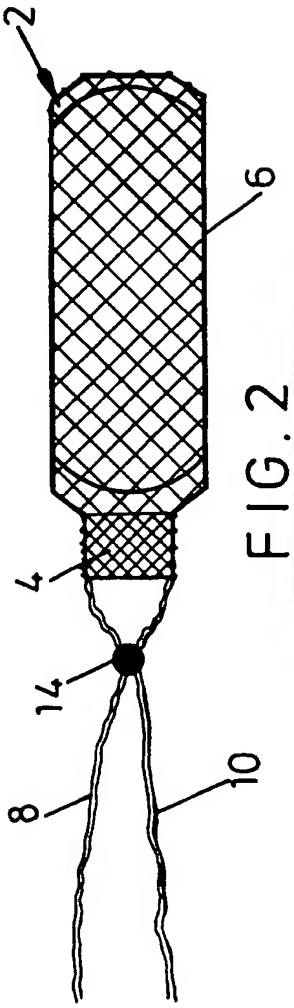


FIG. 2

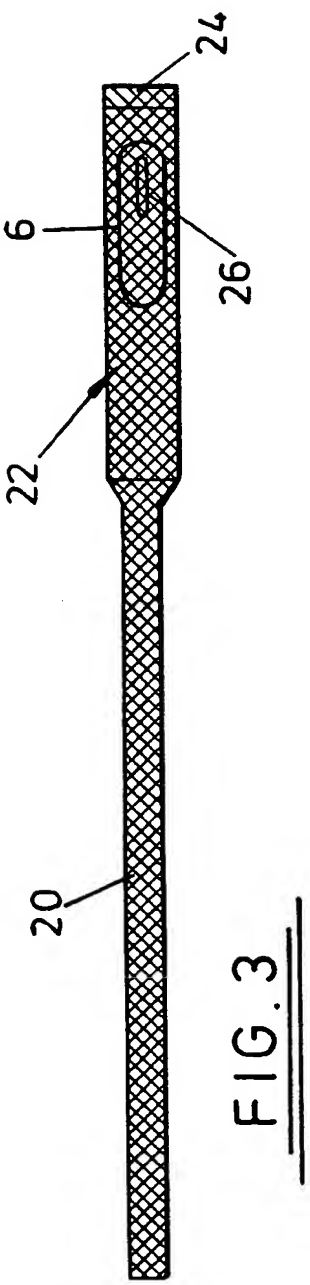


FIG. 3

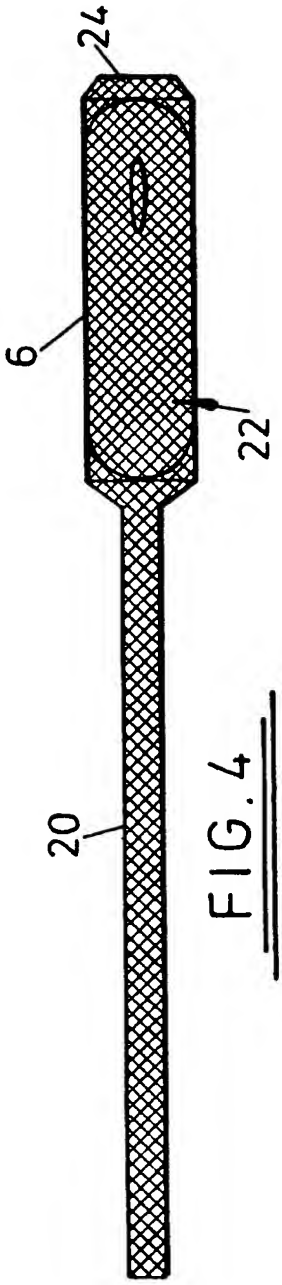


FIG. 4

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# EUROPEAN SEARCH REPORT

Application Number

EP 92 30 6296

## DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document with indication, where appropriate, of relevant passages | Relevant to claim | CLASSIFICATION OF THE APPLICATION (Int. Cl.5) |
|---|---|---|---|
| X<br>Y | GB-A-292 745 (MOTTERAM)<br>* page 1, line 63 - line 75; figure * | 1,2,4<br>3 | A61F6/08 |
| Y | DE-U-9 200 765 (BRITISH TECHNOLOGY GROUP)<br>* claims 3,11 * | 3 | |
| A | WO-A-8 404 666 (SERIMED)<br>* page 3, line 22 - line 26; figures * | 1,5 | |
| A | US-A-2 687 729 (SLAVIN)<br>* column 2, line 7 - line 25; figures * | 1,7 | |
| A | FR-A-2 463 609 (ARRANZ)<br>* claim 1; figures * | 1,8 | |
| A | FR-A-860 975 (CHAPPAZ)<br>* page 1, line 23 - page 2, line 19; figures * | 1 | |

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61F

The present search report has been drawn up for all claims

| Place of search | Date of completion of the search | Examiner |
|---|---|---|
| THE HAGUE | 22 JANUARY 1993 | GODOT T. |

CATEGORY OF CITED DOCUMENTS

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